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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,184	06/13/2007	Satoru Yamagami	01125_1000	3525

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
06/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@dcpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,184	YAMAGAMI ET AL.	
	Examiner	Art Unit	
	KADE ARIANI	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 1/31/2010, has been received and entered.

New claims 16 and 17 have been added.

Claims 1-17 are pending in this application and were examined on their merits.

Specification

Applicant canceled the new matter in the Response filed on 1/31/2010 therefore, the objection to specification under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, is withdrawn.

Claim Objection

Objection to claims 6 and 11 are withdrawn, due to Applicant's amendments to the claims filed on 1/31/2010.

Answer to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of Claims 1, 2, 6-8, and 10 under 35 U.S.C. 102(b) as being anticipated by Amano et al. (in IDS, 2002, Journal of Japanese Ophthalmologic Society, Vol. 106, No.12, p.805-836) as evidenced by Newsome et al. (Invest. Ophthalmol. Vis. Sci.,1982, Vol. 22, p.376-381), is withdrawn due to Applicant's amendments to the claims filed on 1/31/2010.

Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Mimura et al. (cited in IDS of 08/04/2010, Investigative Ophthalmology & Visual Science, September 2004, Vol.45, No.9, p.2992-2997) as evidenced by Inoue et al. (Invest. Ophthalmol. Vis. Sci., 1993, Vol. 34, No. 7, 2313-2315).

Claims 1-5 are drawn to a laminate comprising a transparent type I collagen sheet and a cultured layer of human corneal endothelial cells provided on said sheet, wherein said sheet has a thickness ranging from 5 to 50 micrometers, the transparency of type I collagen sheet is maintained under physiological conditions, transparent type I collagen sheet has an adhesive factor (or bioadhesive layer) on the opposite side from the cultured layer of human corneal endothelial cells and between the transparent type I

collagen sheet and cultured layer of human corneal endothelial cells, and the adhesive factor is human plasma fibronectin.

Claims 6-15 are drawn to a method for manufacturing a laminate of cultured human corneal endothelial cells, comprising preparing a transparent type I collagen sheet having a thickness ranging from 5 to 50 micrometers; and culturing human corneal endothelial cells on said sheet to form a cultured layer of human corneal endothelial, the human corneal endothelial cells are cultured on a transparent type I collagen sheet that has been coated with an adhesive factor, the adhesive factor is human plasma fibronectin, the human corneal endothelial cells are cultured after providing a culture solution containing human corneal endothelial cells on a transparent type I collagen sheet and applying centrifuge force in the direction of said transparent type I collagen sheet, the concentration of human corneal endothelial cells in the culture solution is set to within a range of from $1X10^5$ to $1X10^7$ cells/ml, human corneal endothelial cells have been passaged for 2 to 10 generations, human corneal endothelial cells are cultured under conditions of 37°C and 10 % CO_2, using a cell culturing solution comprising fetal bovine serum, growth factor, and hyaluronic acid in a medium of low glucose concentration.

Claims 16 and 17 are drawn to a method of transplanting a laminate comprising a transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness and a cultured layer of human corneal endothelial cells provided on said sheet, wherein said sheet, comprising inserting the laminate into the anterior chamber, and fixing the inserted laminate to the posterior corneal stroma.

Mimura et al. disclose a method for manufacturing a laminate of cultured human corneal endothelial cells, comprising preparing a transparent type I collagen sheet having a thickness ranging from 5 to 50 micrometers and culturing human corneal endothelial cells on said sheet to form a cultured layer of human corneal endothelial, and a laminate comprising a transparent type I collagen sheet and a cultured layer of human corneal endothelial cells provided on said sheet wherein said sheet has a thickness ranging from 5 to 50 micrometers (each sheet was 40 -50 μm thick), the human corneal endothelial cells are cultured after providing a culture solution containing human corneal endothelial cells on a transparent type I collagen sheet and applying centrifuge force in the direction of said transparent type I collagen sheet, and the concentration of human corneal endothelial cells in the culture solution is set to within a range of from $1X10^5$ to $1X10^7$ cells/ml (p.2993 1st column 2nd paragraph lines 1-3 and 8 and 3rd paragraph lines 1-4), the transparency of type I collagen sheet is maintained under physiological conditions (p.2994 2nd column 4th paragraph lines 6-7), transparent type I collagen sheet has an adhesive factor on the opposite side from the cultured layer of human corneal endothelial cells and between the transparent type I collagen sheet and cultured layer of human corneal endothelial cells, and the adhesive factor is human plasma fibronectin (p. 2993 1st column last paragraph lines 16-17and p.2995 2nd column last paragraph lines 2-5). Mimura et al. further disclose human corneal endothelial cells have been passaged for 2 to 10 generations (p.2993 1st column 1st paragraph line 2), human corneal endothelial cells are cultured under conditions of 37°C and 10 % CO_2, a cell culturing solution comprising fetal bovine serum, growth factor, and hyaluronic acid

in a medium of low glucose concentration, and using bovine ECM (p.2992 2nd column 2nd paragraph "Materials & Methods" lines 1-2and 7-8, and 3rd paragraph line 8). It must be noted that because hyaluronic acid or HA is a major constituent of extracellular matrix (also called ECM) (see Inoue et al. p.2313 Introduction 1st column lines 1-4), and since Mimura et al. disclose culturing using bovine extracellular matrix therefore, Mimura et al. meets the claimed hyaluronic acid.

Mimura et al. also disclose a method of transplanting a laminate comprising a transparent type I collagen sheet ranging from 5 to 50 micrometers in thickness and a cultured layer of human corneal endothelial cells provided on said sheet, wherein said sheet, comprising inserting the laminate into the anterior chamber, and fixing the inserted laminate to the posterior corneal stroma (p.2993 1st column last paragraph lines 18-20).

Mimura et al. therefore clearly anticipate the claimed laminate, method for manufacturing a laminate of cultured human corneal endothelial cells, and method of transplanting a laminate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Amano et al. (in IDS, 2002, Journal of Japanese Ophthalmologic Society, Vol. 106, No.12, p.805-836) in view of Civerchia (US Patent No. 5,716,633) and further in view of Miyata et al. (Cornea, 2001, Vol. 20. No.1, p.59-63) and Inoue et al. (Invest. Ophthalmol. Vis. Sci., 1993, Vol. 34, No. 7, 2313-2315), is withdrawn due to Applicant's amendments to the claims filed on 1/31/2010.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651